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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,770	05/24/2007	Gloria Astrid Limb	GJE.1057	7263
23557 7590 07/20/2011 SALIWANCHIK, LLOYD & EISENSCHENK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER CROUCH, DEBORAH				
ART UNIT 1632		PAPER NUMBER		
NOTIFICATION DATE 07/20/2011		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@uspatents.com

Office Action Summary

Application No.

10/580,770

Applicant(s)

LIMB ET AL.

Examiner

Deborah Crouch

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's arguments filed May 5, 2011 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1, 2, 4-6, 8 and 11-13 are pending. Claims 8 and 11 -13 are withdrawn from consideration as to a non-elected invention. Claims 1, 2 and 4-6 are examined herein.

The rejections made under 35 U.S.C. § 102/103 in the office action mailed over Kelly et al and Walcott et al, or 102(b) over Kelly are withdrawn. .

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 4-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Limb et al, Investig. Ophthal. & Visual Sci., 2002, Vol. 43, pp. 864-869 (IDS, filed 11/3/10, Ref. R1) in view of Kelley et al. Invest. Ophthal. Vision Sci., 1995, Vol. 36, pp. 1280-1289 as set forth in the rejection mailed January 5, 1951.

Limb teaches a culture of adult human Muller cells expressing markers EGF-R, glutamine synthetase, CRALBP and α -SMA (page 866, col. 1, parag. 1, lines 2-8). Limb also teaches the culture of adult Muller cells on fibronectin (page 865, col. 1, parag. 3, lines 1-6). The cells were derived from the retina donated by a human adult (page 865, col. 1, parag. 2, lines 4-10). Further the cells described by Limb have the same marker expression pattern as the cells disclosed, indicating for the breadth of the claims, the cells are the same.

Kelly teaches the culture of human fetal retinal cells on Matrigel™ coated tissue culture plates in media containing EGF (page 1282, col. 2, parag. 3, lines 1-6). The retinal cells are described as comprising Muller cells, which would be de-differentiated to a progenitor phenotype. Kelley offers motivation in stating human fetal retinal progenitor cells can be used to identify molecules involved in factors that control retinal neurogenesis. Further, Kelley cultures the retinal cells comprising Muller cells in media comprising retinoic acid where the exhibit the expression of recovering, a protein associated with photoreceptor cells (page 1284, col. 1, parag. 3, lines 1-8 and col. 2, parag. 1, lines 1-5).

Thus at the time of the instant invention, the ordinary artisan would have found it obvious to culture adult Muller cells, as taught by Limb et al under the conditions taught by Kelley et al on matrigel or fibronectin matrix in the presence of EGF to determine the effect of such culture on cell morphology.

Applicant argues Kelly is directed to fetal human retinal progenitors and do not identify Muller cells expressing mature markers. Applicant argues Kelly did not identify the cell population as comprising Muller cells or Muller stem cells, and in fact identified the cells as neurons by staining with NSE. Applicant argues the cells taught by Kelley do not express markers of mature Muller cells. Applicant also argues the cells of Kelley cannot be growth indefinitely... These arguments are not persuasive

While the cells taught by Kelly and those claimed are from different stages of development, fetal vs. adult, there is no evidence the two cell types do not express the same markers, or that Kelly's cell line cannot be expressed indefinitely. Applicant offers

arguments for such but no evidence in the form of a declaration under 35 U.S.C. § 1.132 or references. Kelly, through the growth of the cell population that contains Muller cells in the presence of EGF, shows the fetal cells at least express the EGFr, which Limb teaches is a marker of mature Muller cells. Thus, while Kelly did not test for the markers stated by applicant, there is no reason to believe the markers are not present, and every reason to believe the EGFr mature Muller cell marker is present. Further, Kelly states the flattened cell in the culture were probably Muller cells and expressed NSE at a much lower level (Kelly, page 1282, col. 1, parag. 1, lines 14-17). Thus, Kelly believed the culture to contain Muller cells. There is no requirement in the claims for the cultures to be any amount of Muller cells. Therefore Kelly is an appropriate reference. Applicant should amend the claims to a purity level and/or add a step for identifying or isolating the dedifferentiated cell. The re-differentiation step would be better served if written independently.

Applicant argues Limb describes a characterization of a spontaneously immortalized Muller cell line. Applicant argues when the article was published, it was not known that the cells of the cell line were stem cells. Applicant argues because Lim did not teach the stem cell nature of cells, one of ordinary skill would have not been motivated to combine the teachings of Kelley and Limb et al. publication to reach the claimed invention. These arguments are not persuasive.

Again applicant should carefully read the claims. For example there is no separation of the dedifferentiation step from the re-differentiation step. Both events can be performed simultaneously. Further, the cells taught by Limb are adult Muller cells

and in view of Kelly when cultured in the presence of EGF would become dedifferentiated cells. There is no requirement in the claims to identify, purify, and substitute media or any step that removes the invention from Kelly and Limb. The ordinary artisan would have been motivated to combine Kelly and Limb to determine the effect as there is no requirement to combine for the same purpose as the invention being examined.

Should applicant wish to discuss the language of the claims, there representative is invited to call at the number given below.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

July 17, 2011